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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,264	03/12/2004	Don Fishbein	52427-AA/JPW/GJG	8229

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EXAMINER	
HUGHES, ALICIA R	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/799,264	FISHBEIN, DON	
	Examiner	Art Unit	
	Alicia R. Hughes	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *(3 sheets)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims and Examination

Claims 30-45 are pending and the subject of this Office Action. Applicant cancelled claims 1-29 in the response filed on 25 November 2005.

Applicants' argument, filed on 30 October 2006, has been fully considered and it is deemed to be persuasive regarding the previous rejection. Therefore, rejections and objections not reiterated from previous Office Actions are hereby withdrawn.

Unfortunately, upon reconsideration of the pending claims, as presented, the following new rejections are applied. They constitute the complete set of rejections being applied to the instant application presently.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 30-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 30-45 of copending Application No. 10/799,197. Although the conflicting claims are not identical, they are not patentably distinct from each other because but for the phraseology "burn-induced trauma" in claim 30 of '264 as opposed to the phraseology "post-burn catabolism" in claim 30 of the '197 are the only variations in the pending claims. Importantly, the burn-induced trauma of '264 is inclusive of the time period wherein a burn occurs and as well, the post-burn period and the time after which burn trauma may be present. Moreover, the patient may be healed from the burn and no longer have burn-induced trauma, but nevertheless continue to suffer from weight loss caused by the burn. Given the overlapping of the subject matter, one application appears to be an obvious variant of the other, making this rejection a proper one.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections – 35 U.S.C. §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 30-40 and 42-45 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,090,799 [hereinafter referred to as "Berger"] in view of U.S. Patent No. 4,456,596 [hereinafter referred to as "Schaffer"].

Berger teaches that "[a]nabolic steroids, as a class, are known to stimulate appetite" (Col. 2, lines 64-65, and furthermore, that oxandrolone, increases protein synthesis (Col. 3, lines 4-5). Berger also teaches that "[i]mproved nutrition is important to individuals with AIDS who have experienced loss of lean body mass" (Col. 2, lines 65-67). Berger also teaches the administration of oxandrolone, in a daily dosage of about 2.5 milligrams ["mg"] to about 80 mg (Abstract; Col. 2, lines 14-18; Col. 3, lines 30-38; Col. 5, lines 41-49). Through the administration of oxandrolone, "[l]oss in muscle mass (wasting) is attenuated, and body weight can be more readily maintained in this manner ... revers[ing] weight loss" (Col. 2, lines 1-5; see also, the Example at Col. 7, lines 33-57 – Col. 8, lines 1-24).

Oxandrolone is an anabolic steroid with numerous synonymous chemical names, including 17β-Hydroxy-17α-methyl-2-oxa-5α-androstan-3-one, as disclosed in claim 42 of the present invention. See display from Chemical Abstract Service Registry enclosed.

Berger also teaches that "[o]xandrolone preferably is administered orally; however, other routes of administration can be utilized as well" (Col. 2, lines 8-9). The Berger invention teaches oxandrolone combined with solid or liquid pharmaceutical carriers and formulated using pharmacologically acceptable excipients, or dissolved or suspended in physiologically acceptable solvents or liquid vehicles for oral, percutaneous, or topical administration (Col. 3, lines 19-25). "Examples of suitable unit dosage forms in accordance with this invention are tablets, pills, powder, packets, wafers, cachets, segregated multiples of any of the foregoing, transdermal patches, aliquots of injectables, and like forms" (Col. 4, 35-39).

Berger does not teach the use of anabolic steroids in the treatment of burns. However, Schaffer teaches that the use of topically or systemically applied drugs, such as anabolic steroids, "for ... healing processes of physically, chemically or physiologically induced tissue lesion, such as burns, ... accelerate the healing process of tissue injuries" (Col. 1, lines 10-19).

One of ordinary skill in the art would be motivated to combine the teachings of Berger and the teachings of Schaffer, because the patents teach overlapping subject matter, namely treatment using anabolic steroids. In light of the foregoing, and absent any evidence to the contrary, one would conclude that it would have been *prima facie* obvious to one of ordinary skill in the art that the administration of oxandrolone, in the dosages and dosage forms disclosed in the present invention, would be an effective method for promoting weight gain after weight loss for one who experiences loss of lean body mass due to burn-induced trauma.

Claims 30 and 41 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 6,090,799 [hereinafter referred to as "Berger"] in view of U.S. Patent No. 4,456,596 [hereinafter referred to as "Schaffer"] and in further view of U.S. Patent No. 5,434,146 [hereinafter referred to as "Labrie et al"].

The teachings of Berger, *supra*, are incorporated herein by reference, but Berger does not teach the administration of oxandrolone in a sustained release formulation. Labrie et al teach the administration of certain anabolic steroids, including oxandrolone, in a sustained release formulation (Abstract; Col. 21, lines 17 and 61-68).

One of ordinary skill in the art would be motivated to combine the teachings of Berger and Schaffer with the teachings of Labrie et al., due to their overlapping subject matter, most notably anabolic steroids. In view of the foregoing and absent any express evidence to the contrary, it would have been prima facie obvious to one of ordinary skill in the art that the administration of an effective amount of oxandolone in sustained release formulations would be effective for promoting weight gain after weight loss resulting from burn-induced trauma in a patient.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia Hughes whose telephone number is 571-272-6026. The examiner can normally be reached from 9:00 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR of Public PAIR. Status information for unpublished applications is available through Public PAIR only. For information about the PAIR system, see http://pair-direct-uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

6 February 2007
ARH

3/2/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER